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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/652,372

08/29/2003

Enno Adema

03-769

1588

48801

7590

10/24/2006

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EXAMINER

LUM, LEON YUN BON

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/652,372

Applicant(s)

ADEMA, ENNO

Examiner

Leon Y. Lum

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 6-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, species A(i), and species B(i), claims 1-2, 4, and 6-12 in the reply filed on July 28, 2006 is acknowledged. However, upon further consideration, claims 13-15 have been **rejoined** with the elected claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 4, 6-7, and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Plattner et al (US 4,219,497).

Plattner et al teach a kit the method of measuring total AT-III activity by taking advantage of the fact that AT-III inhibits human α -thrombin and heparin potentiates the activity of AT-III, wherein it is possible to delineate the inhibition of thrombin by AT-III from other plasma proteins (i.e. thrombin essentially does not interact with AT but interacts with interfering factor) by measuring a reaction mixture between thrombin and a chromogenic substrate (i.e. adding a second reagent R2; suitable for immunological

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determination) through measuring total AT-III as an entity (i.e. adding third reagent R3 to change the conditions such that the AT binding partner interacts with AT and conducting a second determination of free fraction of AT binding partner; R3 separate from R1) distinct from the "progressive anti-thrombin activity" measured in the absence of heparin (i.e. first determination of free fraction of AT binding partner), such that the amount of AT-III and the amount of color produced from the substrate cleavage by thrombin are inversely proportional, and the level of AT-III can therefore be readily determined (i.e. determining the AT content in the sample from the difference between the first and second determinations of the free fraction of thrombin; kinetic determination). See column 6, line 28 to column 7, line 6.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plattner et al (US 4,219,497) in view of Exner (US 6,051,434).

Plattner et al reference has been disclosed above, but fails to teach that the first reagent R1 comprises polybrene.

Exner teaches a mixture including polybrene, in order to reverse the effect of any heparin that may be present in test samples. See column 3, lines 34-37.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include polybrene, as taught by Exner, in the step of measuring the progressive anti-thrombin activity, as taught by Plattner et al, in order to reverse the effect of any heparin that may be present in test samples. Since the measurement step of Plattner et al requires determining the activity of anti-thrombin in the absence of heparin, the inclusion of polybrene would ensure the success of the assay, thereby providing motivation to combine Plattner et al and Exner references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the polybrene of Exner in the method of Plattner et al, since Plattner et al teach measurement steps excluding thrombin:AT-III interaction, and the polybrene of Exner is well known in the art as capable of preventing the effect of heparin on inducing thrombin:AT-III complexes.

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7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Plattner et al (US 4,219,497) in view of Nesheim et al (US 5,308,755).

Plattner et al reference has been disclosed above, but fails to teach an additional AT binding partner.

Nesheim et al teach the addition of purified Factor Xa, in order to perform a competition assay with heparin for antithrombin III to determine the level of heparin activity. See column 2, line 51 to column 3, line 2.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Plattner et al with the addition of purified Factor Xa, as taught by Nesheim et al, in order to perform a competition assay with heparin for antithrombin III to determine the level of heparin activity. Determining the level of heparin activity, as taught by Nesheim et al, would indicate the extent of interaction heparin has with the relationship between thrombin and antithrombin III, as taught by Plattner et al, thereby providing the motivation to combine Plattner et al and Nesheim et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the step of Nesheim et al in the method of Plattner et al, since both Plattner et al and Nesheim et al teach homogenous assays that include heparin and antithrombin III.

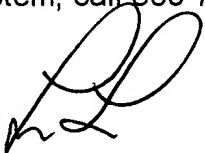
Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon Y. Lum
Patent Examiner
Art Unit 1641



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